EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Unit for Information and Communications Technology

Expression of interest for software development companies

Creating electronic drug information for prescribing in the European Union

In 2009, the European Medicines Agency initiated a research project evaluating the viability and uses of an electronic summary of product characteristics (e-SPC).

The e-SPC project aims to enhance patient safety, drug efficacy and to improve pharmacotherapy by making the prescribing process more customised to individual patients' needs. This customisation will help in prescribing the most appropriate drug and dosage, taking data from each individual patient into account, and thereby possibly preventing adverse drug reactions. A rational choice of the right drug and dosage will prevent adverse reactions, improve health care and decrease costs.

The scope of this project thus far has been to:

- Identify European Union (EU) physicians' needs for drug information on a comprehensive level (in a limited number of EU countries)
- Evaluate how these needs may be fulfilled by a structured SPC capable of interacting with electronic media
- Provide a well-documented information model presenting the structure and format for the e-SPC, focussing on specific therapeutic areas and specific parts of the SPC.
- Test the model with a limited number of users

The implementation of the model in EU countries and the administration of data and information systems generated upon completion of the project were out of the scope of this project.

The first phase of the project was completed during the first quarter of 2011.

In light of this, it is our belief that to achieve this goal, all the following parties[1] should be involved:

- Prescribing physicians;
- Drug buyers/patients;
- Health-technology-assessment bodies;

[1] The list of parties is not exhaustive
[2] eSPC Meeting Q4 2011

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- The pharmacovigilance community;
- Experts concerned with quality monitoring of health care (e.g. hospital managers);
- Regulatory agencies, including national competent authorities and the European Medicines Agency;
- The pharmaceutical industry.

This list of parties involved must also include providers of information and communication technology (ICT) solutions in this area, in order to use their experience and knowledge to:

- Understand why the future EU e-SPC model will be useful to stakeholders;
- Illustrate how this EU e-SPC will be used or has been used in the development of the complimentary building blocks of electronic health care;
- Understand the needs of collaboration with software developers who might be working with future working models of the e-SPC.

In order to achieve these objectives, the Agency would like to find out whether software development companies would be interested in participating in a workshop with the e-SPC consortium to discuss the future of electronic prescribing in the EU.

The event will take place on 5 October 2011 at the European Medicines Agency in London.

The Agency will not be able to finance software development companies' participation at this meeting. Software companies with e-SPC initiatives and solutions should request participation at this meeting.

The attached form needs to be filled in by those software companies requesting participation. This form should be sent to the attention of Natasha Brown at the following e-mail address: natasha.brown@ext.ema.europa.eu.